MAR 2 8 2005

K042626

510(K) SUMMARY
NeuroPort™ NSP System

Submitter Name:	Cyberkinetics, Inc.
Submitter Address:	100 Foxborough Boulevard, Suite 240 Foxboro, MA 02035
Contact Person:	Nandini Murthy, V.P. Regulatory Affairs and Quality Systems
Phone Number:	(508) 549-9981, Extn 103
Fax Number:	(508) 549-9985
Date Prepared:	Sept 24, 2004
Device Trade Name:	NeuroPort™ NSP System
Device Common Name:	Neural Signal Amplifier
Predicate Devices:	BMSI 5000 (Nicolet), Ceegraph (Bio-Logic) and EMU 128 (XLTek)
Device Description:	The Neuroport Neural Signal Processing (NSP) System is intended for recording and monitoring. Its functionality includes routine brain activity recording, monitoring, retrieval and replay. The Neuroport supports up to 96 channels of recording and is comprised of the following hardware components: Patient Cable, Amplifier, CPU and a Display monitor. The Neuroport System also includes the following software functions: acquisition, amplification and display.
Intended Use:	The NeuroPort™ NSP System is intended for temporary (<30 days) recording and monitoring of brain electrical activity.
Performance Data:	The NeuroPort™ NSP conforms to the relevant safety standards for intra-operative and hospital monitoring settings: IEC 60601-2-26, IEC 60601-1-2, UL 2601-1, CAN/CSA-C22.2 no. 601.1-M90.
Conclusion:	The NeuroPort™ Neural Signal Processing (NSP) System has similar indications statements as the predicate devices. All are used for monitoring brain electrical activity. The functionality of the Neuroport NSP System and predicate devices is identical and includes routine brain activity recording, amplification, digitization, monitoring, retrieval and display. Therefore the Neuroport NSP is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Nandini Murthy
Vice President, Vice President Regulatory Affairs
and Quality Systems
Cyberkinetics, Inc.
100 Foxborough Boulevard, Suite 240
Foxborough, Massachusetts 02035

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Re: K042626
Trade/Device Name: Neuroport™ Neural Signal Processor System
Regulation Number: 21 CFR 882.1400, 21 CFR 882.1835
Regulation Name: Electroencephalograph; Physiological signal amplifier
Regulatory Class: II
Product Code: FYX and GWL
Dated: February 8, 2005
Received: February 9, 2005

Dear Ms. Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042626

Device Name: Neuroport™ Neural Signal Processor System

Indications For Use:

The intended use of the Cyberkinetics, Inc. Neuroport Neural Signal Processor System is for temporary (<30 days) recording and monitoring of brain electrical activity.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042626